

**IN THE UNITED STATES DISTRICT COURT FOR  
THE EASTERN DISTRICT OF LOUISIANA**

**IN RE: ZOSTAVAX (ZOSTER VACCINE  
LIVE) PRODUCTS LIABILITY  
LITIGATION**

Civil Action No.: \_\_\_\_\_

KATHLEEN NIEMIC,

Plaintiff,

vs.

MERCK & CO., INC. and MERCK SHARP &  
DOHME, CORP.,

Defendants.

**COMPLAINT**

Plaintiff, Kathleen Niemic, by and through Plaintiff's attorneys, MORRIS BART, LLC complains and alleges against Defendants MERCK & CO., INC. and MERCK SHARP & DOHME, CORP. (collectively, "Defendants" and/or "Merck"), on information and belief, as follows:

**PARTIES**

1. Plaintiff, Kathleen Niemic, ("Plaintiff") at all times relevant to this action was and is a resident and citizen of the State of Louisiana, St. Tammany Parish.

2. Defendant MERCK & CO., INC. is incorporated in New Jersey with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey. At all times relevant to this action, Defendant MERCK & CO., INC. developed, tested, designed, set

specifications for, licensed, manufactured, prepared, compounded, assembled, packaged, processed, labeled, marketed, promoted, distributed, and/or sold the Zostavax vaccine to be administered to patients throughout the United States, including the District. Merck has conducted business and derived substantial revenue within the District, including, but not limited to, its business activities related to the Zostavax vaccine.

3. Defendant MERCK SHARP & DOHME CORP. is a wholly-owned subsidiary of Defendant MERCK & CO., INC. and part of the MERCK & CO., INC. family of companies. Defendant MERCK SHARP & DOHME CORP. is incorporated in New Jersey with its headquarters located at 2000 Galloping Hill Road, Kenilworth, New Jersey. At all times relevant to this action, Defendant MERCK SHARP & DOHME CORP., developed, tested, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, packaged, processed, labeled, marketed, promoted, distributed, and/or sold the Zostavax vaccine to be administered to patients throughout the United States, including the District. Defendant MERCK SHARP & DOHME CORP. has conducted business and derived substantial revenue within the District, including, but not limited to, its business activities related to the Zostavax vaccine.

4. Furthermore, based upon information and belief, Merck is, and was at all times relevant hereto,

- a. duly authorized to conduct business in the District;
- b. regularly conducted and solicited business within the District and continues to do so;
- c. does business in the District, and at all times relevant hereto, has sold and distributed the Zostavax vaccine in the District;
- d. derives substantial revenue from goods used or consumed in the District;

- e. advertised its Zostavax vaccine to patients, doctors and hospitals in the District and/or other medical facilities located in the District;
- f. advertises or otherwise promotes its business in the District; and
- g. reasonably expects to be subject to the District's product liability law.

### **JURISDICTION AND VENUE**

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds \$75,000.00, exclusive of interest and costs, and because complete diversity of citizenship exists between the Plaintiff and the Defendants.

### **NO FEDERAL PREEMPTION**

6. The National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 et seq. does not preempt Plaintiff from filing this Complaint. Pursuant to §11(c)(1)(A) of the Vaccine Act, the Vaccine Court has jurisdiction to only hear cases listed on the Vaccine Injury Table. The Zostavax vaccine is not a vaccine listed in the Vaccine Injury Table.

### **FACTS**

7. At all times hereinafter mentioned, Merck designed, manufactured, licensed, labeled, tested, distributed, marketed and sold the Zostavax vaccine.

8. Zostavax was designed, developed, marketed, and sold with the intended purpose of preventing shingles, which is caused by the varicella zoster virus ("VZV").

9. Varicella zoster is a virus that causes chickenpox.

10. Once the VZV causes chickenpox, the virus remains inactive (dormant) in the nervous system for many years.

11. VZV can be reactivated due to factors such as disease, stress, aging, and immune modulation caused by vaccination.

12. When reactivated, VZV replicates in nerve cells and is carried down the nerve fibers to the area of skin served by the ganglion that harbored the dormant virus.

13. In May of 2006, the U.S. Food and Drug Administration (“FDA”) approved the Zostavax vaccine to be marketed and sold in the United States by Merck.

14. Zostavax was initially indicated for the “the prevention of herpes zoster (shingles) in individuals 60 years of age and older when administered as a single-dose.” FDA Approval Letter, May 25, 2006.

15. FDA approval was based in large part on the results of the Shingles Prevention Study (SPS) supported by Merck.

16. The results of the SPS were published in the New England Journal of Medicine on June 2, 2005. The paper was titled “A Vaccine to Prevent Herpes Zoster and Postherpetic Neuralgia in Older Adults”. N. Engl. J. Med. 2005; 352(22):2271-84.

- a. Shingles results from reactivation of latent varicella zoster virus (VZV), which is the virus that causes chickenpox. The incidence and severity of shingles increases as people age.
- b. As further described in this paper, “[t]he pain and discomfort associated with herpes zoster can be prolonged and disabling, diminishing the patient’s quality of life and ability to function to a degree comparable to that in diseases such as congestive heart failure, myocardial infarction, diabetes mellitus type 2, and major depression.” N. Engl. J. Med. 2005; 352(22) at 2272.

- c. The Zostavax vaccine is essentially the same vaccine as that used for
- d. chickenpox, except significantly stronger.
- e. Zostavax contains live VZV. The virulence of the virus is reduced or “attenuated”. Attenuated vaccines are designed to activate the immune system with the decreased risk of actually developing the disease.
- f. Zostavax is developed from a live attenuated version of the Oka/Merck VZV vaccine strain.
- g. One of the paper’s more significant findings was “[t]he greater number of early cases of herpes zoster in the placebo group, as compared with the vaccine group, and the fact that no vaccine virus DNA was detected, indicate that the vaccine did not cause or induce herpes zoster.”

17. A risk of using a live virus vaccine is that it is not weakened enough or “under-attenuated”.

18. Under-attenuated live virus creates an increased risk of developing the disease the vaccine was to prevent.

19. Under-attenuated live VZV has been shown to reactivate. Leggiadro, R. J. (2000). Varicella Vaccination: Evidence for Frequent Reactivation of the Vaccine Strain in Healthy Children. *The Pediatric infectious disease journal*, 19(11), 1117–1118; Krause, P. R., & Klinman, D. M. (2000). *Nature Medicine*, 6(4), 451–454.

20. Once injected, attenuated live virus has been shown to recombine into more virulent strains causing disease.

21. Shingles is a reactivation of the latent VZV.

22. The approval granted by the FDA to allow the selling and marketing of this vaccine came with certain post-marketing commitments that Merck agreed to complete to, *inter alia*, ensure the safety of this vaccine. These commitments included the following:

- a. A randomized, placebo-controlled safety study to assess the rates of serious adverse events in 6,000 people receiving the vaccine as compared to 6,000 who receive a placebo.
- b. An observational study using a health maintenance organization (HMO) and 20,000 vaccinated people to address safety issues in the course of clinical practice. This study is specifically to detect “potential safety signals following administration of Zostavax.” This study was to be submitted to the FDA by December 2008.

23. Since the publication of the SPS in the New England Journal of Medicine, there have been questions raised regarding the safety of Zostavax vaccine in scientific and medical journals.

24. Zostavax is a stronger, more potent version of Merck’s chickenpox vaccine, Varivax.

25. Varivax contains a minimum of 1,350 PFU (plaque-forming units) of the virus while Zostavax contains a minimum of 19,400 PFU.

26. In the clinical studies evaluating Zostavax, more than 90% of the vaccinated subjects received 32,300 PFU.

27. Merck added several adverse reactions to its package insert/prescribing information since Varivax was approved.

- a. The biological system in which the most adverse reactions were added was

the nervous system.

- b. Added reactions include: encephalitis, cerebrovascular accident, transverse myelitis, Guillain-Barré syndrome, Bell's palsy, ataxia, non-febrile seizures, aseptic meningitis, dizziness, and paresthesia.
- c. Acute Disseminated Encephalomyelitis is a type of encephalitis.

28. As of February 2014, the patient information sheet, label, and prescribing information distributed with the Zostavax vaccine contain no clear reference to the potential risk of viral infection.

29. Individuals with compromised immune systems should not receive a live virus vaccine because those individuals can develop the disease that the vaccine is designed to prevent.

30. The patient information sheet, as well as the label and prescribing information for Zostavax at all times relevant hereto, did not adequately, if at all, address the risk of viral infection. All that was addressed is the concern that a rash and itching might develop at the injection site. This is despite the fact that shingles was a noted occurrence during clinical trials of the vaccine.

31. The prescribing information for Zostavax contains a warning that "[t]ransmission of vaccine virus may occur between vaccinees and susceptible contacts".

- a. The risk of transmission of vaccine virus is due to active viral infection in individuals receiving the Zostavax vaccine.

32. The patient information sheet, as well as the label and prescribing information for Zostavax at all times relevant hereto, did not adequately, if at all, address the risk of viral infection or possible diseases of the nervous system. This is despite the fact that Varivax, a less

potent vaccine, has added several neurological diseases and symptoms as adverse reactions to the Varivax vaccine.

33. Since Zostavax's introduction in 2006, vaccine adverse event reports (VAERs) appeared in significant numbers addressing various adverse effects, including, but not limited to, viral infection resulting in disease of the central nervous system, including acute disseminated encephalomyelitis and acute transverse myelitis.

34. Other than postherpetic neuralgia, shingles can lead to other serious complications, such as scarring, bacterial superinfection, allodynia, cranial and motor neuron palsies, pneumonia, encephalitis, visual impairment, hearing loss, and death.

35. It follows that given the increased risk of viral infection due to vaccination, such complications are also possible complications of Zostavax. It also follows that post-vaccination viral infection can cause significant issues in the nervous system due to the replication of the latent virus in the nervous system.

36. Despite this information and the potential correlation between being administered the Zostavax vaccine and within a relatively short period of time developing an infection, leading to the development of shingles or varicella-zoster virus pneumonia, Merck failed to properly address and provide this information both to the patient and the medical providers prescribing the vaccine.

37. In October 2017, the FDA approved Shingrix – an alternative shingles vaccine manufactured by GlaxoSmithKline. Shingrix was created by extracting a glycoprotein located on the surface of the varicella zoster virus. This glycoprotein triggers the body's immune system to activate and fight against the varicella zoster virus. The glycoprotein itself, however, cannot infect the body as it is not a virus. GlaxoSmithKline added the extracted glycoprotein with an



adjuvant, a substance that enhances the body's immune response to an antigen, to create Shingrix. When Shingrix enters the body, the vaccine induces an immune response that cannot directly infect the vaccinated human host nor activate dormant VZV virus. In direct contrast, Zostavax contain various mutated live strains of actual VZV virus which can directly infect the vaccinated human host and/or activate dormant VZV virus.

38. Shingrix was proven to be safe and effective to prevent shingles in over 90% of users in contrast to Zostavax's effectiveness rates that were as low as 18% in certain age groups. Shingrix was proven to stay effective in preventing shingles at least four years in contrast to Zostavax's effectiveness that waned over a five year period.

39. The safety, effectiveness, and the simple superiority of the design of Shingrix over Zostavax allowed the Center for Disease Control ("CDC") to make an unprecedented decision to recommend Shingrix over Zostavax to the general public after only a few days of Shingrix being approved by the FDA.

40. Upon information and belief, Merck possessed, or should have possessed, the knowledge to create a Shingles vaccine similarly designed as Shingrix.

### **CASE-SPECIFIC FACTS**

41. Plaintiff at all times relevant to this action was and is a citizen of the state of Louisiana, residing in Lacombe, St. Tammany Parish.

42. Plaintiff was inoculated with Defendants' Zostavax vaccine for routine health maintenance and for its intended purpose: the prevention of shingles (herpes zoster).

43. After receiving Defendants' Zostavax vaccine, on 1/16/2016, plaintiff developed a severe case of shingles on her left ear, left eye, and left side of her face. She was treated for months, inserted eye drops every two hours around the clock. Plaintiff now has multiple, debilitating recurrences of viral episodes rendering her unable to work.

44. As a direct and proximate result of Merck's defective Zostavax vaccine, Plaintiff's symptoms have resulted in physical limitations not present prior to using Merck's product. Plaintiff also experiences mental and emotional distress due to resulting physical limitations and seriousness of his condition.

45. As a result of the manufacture, marketing, advertising, promotion, distribution and/or sale of Zostavax, Plaintiff sustained severe and permanent personal injuries. Further, as a tragic consequence of Merck's wrongful conduct, Plaintiff suffered serious, progressive, permanent, and incurable injuries, as well as significant conscious pain and suffering, mental anguish, emotional distress, loss of enjoyment of life, physical impairment and injury.

46. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered and incurred damages, including medical expenses; the loss of accumulations; and other economic and non-economic damages.

47. All damage proximately caused by the aforementioned characteristics of the Zostavax product that rendered the product unreasonably dangerous, arose from the reasonably anticipated use of the product by the Plaintiff.

**COUNT I:**  
**BREACH OF DUTY IN THE MANUFACTURE UNDER THE**  
**LOUISIANA PRODUCTS LIABILITY ACT (LPLA)**

48. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

49. Merck had a duty to exercise reasonable care in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale, and distribution of Zostavax including the duty to take all reasonable steps necessary to manufacture and sell a product that was not defective and unreasonably dangerous to consumers and users of the product.

50. Merck failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions, and distribution of Zostavax because Merck knew, or should have known, that its product caused viral infection, and was therefore not safe for administration to consumers.

51. Merck failed to exercise due care in the labeling of Zostavax and failed to issue to consumers and/or their healthcare providers adequate warnings as to the risk of serious bodily injury, including viral infection, resulting from its use.

52. Merck continued to manufacture and market its product despite the knowledge, whether direct or ascertained with reasonable care, that Zostavax posed a serious risk of bodily harm to consumers. This is especially true given its tenuous efficacy.

53. Merck knew, or should have known, that consumers such as Plaintiff would foreseeably suffer injury as a result of Merck's failure to exercise ordinary care. The characteristic of the product that renders it unreasonably dangerous, the live virus in such a large dosage that the administration of Zostavax can result in the recipient actually getting the disease that the vaccine was built and designed to prevent, including injuries as described in Paragraph 28, existed at the time the product left the control of Merck.

54. As a direct and proximate consequence of Merck's negligence, Plaintiff sustained serious personal injuries and related losses including, but not limited to, the following:

- a. Plaintiff required and will continue to require healthcare and services;
- b. Plaintiff incurred and will continue to incur medical and related expenses; and
- c. Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages.

**WHEREFORE**, Plaintiff demands judgment against Defendants, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

**COUNT II:**  
**MANUFACTURING AND DESIGN DEFECT UNDER**  
**LSA-RS 9:2800.55 AND LSA-RS 9:2800.56**

55. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

56. Merck designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Zostavax vaccine.

57. The Zostavax vaccine was expected to, and did, reach the intended consumers, handlers, and persons coming in contact with the product with no substantial change in the condition in which the product was designed, produced, manufactured, sold, distributed, labeled, and marketed by Merck.

58. The Zostavax vaccine was manufactured, designed, marketed, labeled and sold in a defective condition, for use by Plaintiff's physicians and/or healthcare providers, and all other consumers of the product, making the product unreasonably dangerous.

59. The Zostavax vaccine, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Merck was defective in design and formulation in that when it left the hands of the manufacturers, suppliers, and distributors, the foreseeable risks of harm caused by the product exceeded the claimed benefits of the product.

60. Merck's Zostavax vaccine, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Merck was defective in design and formulation because when it left the hands of Merck, the product was unreasonably dangerous and was also more dangerous than expected by the ordinary consumer.

61. At all times relevant to this action, Merck knew and had reason to know that its Zostavax vaccine was inherently defective and unreasonably dangerous as designed, formulated, and manufactured by Merck, and when used and administered in the form manufactured and distributed by Merck, and in the manner instructed by Merck to be used and administered to Plaintiff and other consumers.

62. Plaintiff's physicians and/or healthcare providers used and administered the Zostavax vaccine for the purpose intended by Merck, and in a manner normally intended to be used and administered, namely for vaccination against shingles (herpes zoster). Merck had a duty to design, create, and manufacture products that were reasonably safe and not unreasonably dangerous for their normal, common, and intended use. Merck's product was not reasonably fit, suitable, or safe for its anticipated use, and safer, reasonable alternative designs existed and

could have been utilized. Reasonably prudent manufacturers would not have placed the product in the stream of commerce with knowledge of these design flaws.

63. Merck designed, developed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product that created an unreasonable risk of serious harm to the health, safety, and well-being of Plaintiff and other consumers. Merck is therefore liable for Plaintiff's injuries and damages sustained proximately caused by Plaintiff's use of the product, as Merck's product unreasonably dangerous, and all damage arose from the reasonably anticipated use of the product by the Plaintiff

64. Plaintiff could not, by the exercise of reasonable care, discover the defective condition of Merck's product and/or perceive its defective dangers prior to its administration by his physicians and/or healthcare providers.

65. Furthermore, Merck defectively manufactured the subject Zostavax vaccine such that it unreasonably increased the risk of contracting an infection from the vaccine.

66. Merck's defective Zostavax vaccine was a substantial, proximate, and contributing factor in causing Plaintiff's injuries.

67. As a proximate result of Merck's acts and omissions and Plaintiff's use of Merck's defective product, Plaintiff suffered serious physical injuries and incurred substantial medical costs and expenses to treat and care for his injuries described in this Complaint, including, but not limited to, the following:

- a. Plaintiff required and will continue to require healthcare and services;
- b. Plaintiff incurred and will continue to incur medical and related expenses; and
- c. Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, and

other losses and damages.

**WHEREFORE**, Plaintiff demands judgment against Defendants, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

**COUNT III: INADEQUATE WARNING UNDER**  
**LSA-RS-9:2800.57**

68. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

69. Merck designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Zostavax vaccine.

70. The Zostavax vaccine was expected to, and did, reach the intended consumers, handlers, and persons coming in contact with the product with no substantial change in the condition in which the product was designed, produced, manufactured, sold, distributed, labeled, and marketed by Merck.

71. The Zostavax vaccine was manufactured, designed, marketed, labeled and sold in a defective condition, for use by Plaintiff's physicians and/or healthcare providers and all other consumers of the product, making the product unreasonably dangerous.

72. Merck researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce its Zostavax vaccine and in the course of same, directly advertised or marketed the product to

consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of its product.

73. Merck's Zostavax vaccine, as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by Merck, was defective due to the product's inadequate warnings and instructions. Merck knew, or should have known, and adequately warned that its product created a risk of serious and dangerous side effects, including but not limited to, viral infection resulting in shingles, postherpetic neuralgia, or other diseases of the nervous system.

74. The product was under the exclusive control of Merck and was unaccompanied by appropriate and adequate warnings regarding the risk of severe and permanent injuries associated with its use, including, but not limited to, the risk of developing a disease in the nervous system due to viral infection. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer.

75. Notwithstanding Merck's knowledge of the defective condition of its product, Merck failed to adequately warn the medical community and consumers of the product, including Plaintiff and his healthcare providers, of the dangers and risk of harm associated with the use and administration of its Zostavax vaccine.

76. Merck downplayed the serious and dangerous side effects of its product to encourage sales of the product; consequently, Merck placed its profits above its customers' safety.

77. The product was defective when it left the possession of Merck in that it contained insufficient warnings to alert Plaintiff and/or his healthcare providers to the dangerous



risks and reactions associated with it, including possible viral infection of the nervous system or another disease of the nervous system.

78. Even though Merck knew or should have known of the risks and reactions associated with their product, it still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

79. Plaintiff used Merck's Zostavax vaccine as intended or in a reasonably foreseeable manner.

80. Merck, as a manufacturer of pharmaceutical products, is held to the level of knowledge of an expert in the field and, further, Merck had knowledge of the dangerous risks and side effects of its product.

81. Plaintiff did not have the same knowledge as Merck and no adequate warning was communicated to his physician(s) and/or healthcare providers.

82. Merck had a continuing duty to warn consumers of its Zostavax vaccine, including Plaintiff, of the dangers associated with its product, and by negligently and/or wantonly failing to adequately warn of the dangers of the use of its product, Merck breached its duty.

83. Although Merck knew, or should have known, of the defective nature of its Zostavax vaccine, it continued to design, manufacture, market, and sell its product without providing adequate warnings and instructions concerning the use of its product so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by its Zostavax vaccine.

84. As a direct and proximate result of Merck's failure to adequately warn or other acts and omissions of Merck described herein, Plaintiff suffered severe and permanent injuries, pain, and mental anguish, including diminished enjoyment of life.

85. Merck's failure to warn extended beyond the product's label and into other media available to Merck, including but not limited to advertisements, person-to-person sales calls, medical journal articles, and medical conference presentations.

86. The Zostavax vaccine, upon information and belief, as manufactured and supplied by Merck, was further defective due to inadequate post-market warnings or instructions because after Merck knew, or should have known, of the risk of serious bodily harm from the administration of its Zostavax vaccine, including, but not limited to, possible viral infection, Merck failed to provide adequate warnings to consumers and/or their healthcare providers about the product, knowing the product could cause serious injury.

87. The Zostavax vaccine, upon information and belief, as manufactured and supplied by Merck, was unreasonably dangerous because an adequate warning about the product was not been provided if, as at the time the product left Merck's control, the product possessed the aforementioned characteristics that may cause damage users such as Plaintiff, and the Merck failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.

88. After Merck had started shipping product that had left its control, Merck acquired knowledge of characteristics of the product that might cause damage and the danger of such characteristic, and is liable for damage caused by a subsequent failure to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product since that knowledge of the characteristics and its danger to users was acquired.

89. A reasonably prudent manufacturer would have warned of these characteristics and its danger to users, and Merck's failure to do so renders defendant liable for all damages caused by Merck's subsequent failure to use reasonable care to provide adequate warning of the danger to Plaintiff and other users of the product.

90. As a proximate result of Merck's acts and omissions and Plaintiff's use of Merck's defective product, Plaintiff suffered serious physical injuries and incurred substantial medical costs and expenses as set forth in this Complaint, including, but not limited to, the following:

- a. Plaintiff required and will continue to require healthcare and services;
- b. Plaintiff incurred and will continue to incur medical and related expenses; and
- c. Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages.

**WHEREFORE**, Plaintiff demands judgment against the Defendants, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

**COUNT IV:**

**NON-CONFORMITY TO EXPRESS WARRANTY UNDER LSA-RS-9:2800.58**

91. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

92. Merck, through its officers, directors, agents, representatives, and written literature and packaging, and written and media advertisements, expressly warranted that its Zostavax vaccine was safe and effective and fit for use by consumers, was of merchantable quality, did not create the risk of or produce dangerous side effects, including, but not limited to, viral infection, and was adequately tested and fit for its intended use.

a. Specifically, Merck stated that “ZOSTAVAX is a vaccine that is used for adults 60 years of age or older to prevent shingles (also known as zoster).”

b. Merck also stated that “ZOSTAVAX works by helping your immune system protect you from getting shingles.”

c. Merck, in the SPS paper, stated that “...the vaccine did not cause or induce herpes zoster.”

93. At the time of making such express warranties, Merck knew and/or should have known that its Zostavax vaccine did not conform to the express warranties and representations and that, in fact, its product was not safe and had numerous serious side effects, including the possibility of viral infection, of which Merck had full knowledge and did not accurately or adequately warn.

94. The Zostavax vaccine manufactured and sold by Merck did not conform to these representations because it caused serious injury, including diseases of the nervous system and/or viral infection, to consumers such as Plaintiff, when used in routinely administered dosages.

95. Merck breached its express warranties because its product was and is defective for its intended purpose.

96. Plaintiff, through plaintiff’s physicians and/or other healthcare providers, did rely on Merck’s express warranties regarding the safety and efficacy of their product in purchasing

and injecting the product, and induced Plaintiff, through plaintiff's physicians and/or other healthcare providers, to use the product, and Plaintiff's damages were proximately caused by the untruthfulness of the express warranty.

97. Members of the medical community, including physicians and other healthcare professionals, relied upon Merck's representations and express warranties in connection with the use recommendation, description, and dispensing of Merck's Zostavax vaccine.

98. As a foreseeable, direct, and proximate result of the breach of the express warranties, Plaintiff suffered severe and permanent personal injuries, harm, and economic loss.

**WHEREFORE**, Plaintiff demands judgment against Defendants, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems proper as well as:

- a. Compensatory damages for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health and medical care costs, lost wages, together with interest and costs as provided by law;
- b. Restitution and disgorgement of profits;

- c. Reasonable attorneys' fees;
- d. The costs of these proceedings;
- e. All ascertainable economic damages;
- f. Punitive damages; and
- g. Such other and further relief as this Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff hereby requests a trial by jury of all issues triable by jury.

Dated: May 18, 2019

Respectfully submitted,

/s Richard L. Root

Richard L. Root La# 19988

Betsy Barnes La# 19473

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